

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1-31 and 55-63 are pending in the application, with 1, 31 and 55 being the independent claims. Claims 1, 13, 15, 27, 29, 31, 55 and 62 are sought to be amended. Support for the amendments can be found in the original claims and throughout the specification. Claims 32-54 and 64-65 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

I. *Claim Rejection Under 35 U.S.C. § 112*

Claims 1-31 and 55-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Office Action, page 2.

A. *Claims 1, 31 and 55*

The Examiner alleges that "Claims 1, 31 and 55 are . . . vague and indefinite as it is not clear if the recitation 'wherein the pore size of said filter increases in the direction of sample flow' means that the filter itself has an increasing pore size or that a first filter in relation to a second filter increases in pore size in relation to the sample flow." Office Action, page 2. Applicants respectfully traverse the rejection.

The M.P.E.P. specifically states that "[b]readth of a claim is not to be equated with indefiniteness." M.P.E.P., 8th ed., § 2173.04 (Rev. 2, May 2004) (*citing In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971)). Here, the rejected claims encompass, for example, embodiments wherein a single filter has an increasing pore size or wherein a first filter in relation to a second filter increases in pore size in relation to the sample flow. As these embodiments were clearly identified by the Examiner, there is nothing vague or indefinite about the language used to define the claims. Moreover, the M.P.E.P. states that "[i]f the scope of the subject matter embraced by the claims is clear, . . . then the claims comply with 35 U.S.C. 112, second paragraph." *Id.* Accordingly, Applicants request that the examiner reconsider and withdraw this rejection.

B. Claim 13

The Examiner states that "[c]laim 13 recites the limitation 'the second filter'. There is insufficient antecedent basis for this limitation in the claim." Office Action, page 3.

Applicants have amended claim 13 and believe that this rejection is now moot. Accordingly, Applicants request that the Examiner reconsider and withdraw the rejection.

C. Claim 15

The Examiner alleges that "[c]laim 15 is vague and indefinite over the recitation of 'pores of sufficient size to shear genomic DNA'. It is unclear what pore size is 'sufficient' to shear genomic DNA. The term 'sufficient' renders the claim indefinite." Office Action, page 3.

Applicants have amended claim 15 and believe that this rejection is now moot.

Accordingly, Applicants request that the Examiner reconsider and withdraw the rejection.

D. Claim 27

The Examiner alleges that "[c]laim 27 is vague and indefinite over the recitation 'said first filter layer is comprised of regenerated cellulose, with a pore size of about .2 μm, and comprised of polyethylene or polypropylene, with an average pore size of about 20 μm'. It is unclear if the first filter layer comprises two separate filters with two different compositions and pore sizes or, in the alternative, if the first filter layer consists of regenerated cellulose fused with polyethylene or polypropylene and encompasses two different pore sizes throughout the filter.'" Office Action, page 3.

Applicants have amended claim 27 and believe that this rejection is now moot.

Accordingly, Applicants request that the Examiner reconsider and withdraw the rejection.

E. Claim 29

The Examiner alleges that "[r]egarding claim 29, the phrase 'and the like' renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by 'and the like'), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05." Office Action, page 3.

Applicants have amended claim 29 and believe that this rejection is now moot.

Accordingly, Applicants request that the Examiner reconsider and withdraw the rejection.

F. Claim 62

The Examiner alleges that "[r]egarding claim 62, the phrase 'e.g.' renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d)." Office Action, page 3.

Applicants have amended claim 62 and believe that this rejection is now moot. Accordingly, Applicants request that the Examiner reconsider and withdraw the rejection.

G. Claim 62

The Examiner alleges that "[c]laim 62 recites the limitation 'said filter layers'. There is insufficient antecedent basis for this limitation in the claim." Office Action, page 3.

Applicants have amended claim 62 and believe that this rejection is now moot. Accordingly, Applicants request that the Examiner reconsider and withdraw the rejection.

II. Claim Rejections Under 35 U.S.C. § 102

The Examiner has rejected claims 1-18, 21-23, 25, 28-31, 55-59, and 61-63 under 35 U.S.C. 102(b) as being anticipated by Jones (WO95/02049). According to the Examiner, "Jones teaches a method of separating biological compounds from cells by filtration using two filters with increasing pore size in the direction of sample flow." Office Action, page 5. Applicants respectfully traverse the rejection.

Solely to expedite prosecution and not in acquiescence to the rejection, claims 1, 31 and 55 have been amended to include the limitation "wherein genomic DNA . . . is

sheared by said filter." Inclusion of this limitation distinguishes Applicants' claims from the applied reference.

The problems associated with genomic DNA when isolating biological macromolecules from cell cultures is set forth by Applicants in paragraph 3 on pages 1-2 of their specification. Approaches to reducing the viscosity of a whole cell lysate by routine genomic DNA shearing methods is problematic. *Id.*

In contrast to these routine methods, an important and distinguishing aspect of Applicants' invention pertains to an improved protocol for the isolation of biological macromolecules which includes shearing genomic DNA. *E.g.*, Specification, page 2, paragraph 4; page 5, paragraph 20; paragraph 43, pages 14-15 and figure 8; paragraph 45, page 15. Accordingly, Applicants' pending independent claims have been amended to include this feature.

In contrast, Jones does not describe shearing genomic DNA. Jones' first filter retains cell debris upon cell lysis, and fails to describe what, if anything, happens to genomic DNA. *See* pages 22-23. In fact, Jones indicates that upon lysis, "[t]he resulting mixture is a cell free lysate of crude DNA with precipitated protein. The cell free lysate of crude DNA is then transferred from chamber 46 to chamber 48 by addition of positive pressure . . ." Page 22, lines 27-30. Hence, the skilled artisan upon reading Jones' protocol would expect that the first filter retained cell debris and allowed genomic DNA to pass through.

After the crude DNA has passed through Jones' first filter, a DNA binding agent is added. Page 22, line 32 to page 23, line 3. The purpose of the second filter (element 49, shown in figure 5) is solely to prevent the DNA (or DNA binding agent) from

flowing through valve 50. Page 23, lines 4-6. Without any reference to shearing genomic DNA, Jones' DNA is eluted from the DNA binding agent and then passes through the second filter. *Id.* at lines 13-17.

To anticipate a claim under 35 U.S.C. §102, a reference must (among other requirements) teach every element of the claim. M.P.E.P., 8th ed., §2131 (rev. May 2004). Because Jones does not teach all of the limitations of Applicants' independent claims as amended, it is respectfully requested that the rejection under 35 U.S.C. §102 be withdrawn.

III. Claim Rejections Under 35 U.S.C. § 103

A. Claims 19 and 24

The Examiner has rejected claims 19 and 24 under 35 U.S.C. 103(a) as being unpatentable over Jones in view of Dewitt (U.S. Patent 6,183,645). Office Action, page 8. Applicants respectfully traverse the rejection.

The Examiner has set forth this rejection by combining the primary reference with DeWitt. However, DeWitt is only offered to teach "the method of phase separation using one or more polypropylene frits (column 3, line 46-50) and . . . the use of the improved apparatus for purification and isolation (column 1, lines 50-64)." Office Action, page 8, third full paragraph.

Solely to expedite prosecution and not in acquiescence to the rejection, claims 1, 31 and 53 are amended to include the limitation "wherein genomic DNA . . . is sheared by said filter." This limitation is not taught or suggested by DeWitt. As described in Section II. above, this feature is also not taught by Jones.

To set forth a *prima facie* case of obviousness under 35 U.S.C. §103, the applied references must (among other requirements) teach or suggest all of the claim limitations. M.P.E.P., 8th ed., § 2143.03 (rev. May 2004). Because neither Jones nor DeWitt teach or suggest all of the claim limitations, it is respectfully requested that the rejection under 35 U.S.C. §103 be withdrawn.

B. Claim 20

The Examiner has rejected claim 20 under 35 U.S.C. 103(a) as being unpatentable over Jones as applied to claim 19 and 24 above, and further in view of Fung et al. (U.S. Patent 6,221,655). Office Action, page 9. The Examiner has set forth this rejection by combining the primary reference with Fung. However, Fung is offered for limited teachings of biological sample filter material, thicknesses, use in a spin filter assembly or with a solid binding matrix. Office Action, page 9, second full paragraph.

Solely to expedite prosecution and not in acquiescence to the rejection, claims 1, 31 and 53 are amended to include the limitation "wherein genomic DNA . . . is sheared by said filter." However, this limitation is not taught or suggested by Fung. As described in Section II. above, this feature is also not taught by Jones.

To set forth a *prima facie* case of obviousness under 35 U.S.C. §103, the applied references must (among other requirements) teach or suggest all of the claim limitations. M.P.E.P., 8th ed., § 2143.03 (rev. May 2004). Because neither Jones nor Fung teach or suggest all of the claim limitations, it is respectfully requested that the rejection under 35 U.S.C. §103 be withdrawn.

C. Claims 26 and 27

The Examiner has rejected claims 26 and 27 under 35 U.S.C. 103(a) as being unpatentable over Jones in view of Sirkar (U.S. Patent 5,053,132). Office Action, page 10. The Examiner has set forth this rejection by combining the primary reference with Sirkar. However, Sirkar is offered for limited teachings of filter material and its alleged properties of enhanced solvent resistance. Office Action, page 10, third full paragraph.

Solely to expedite prosecution and not in acquiescence to the rejection, claims 1, 31 and 53 are amended to include the limitation "wherein genomic DNA . . . is sheared by said filter." However, this limitation is not taught or suggested by Sirkar. As described in Section II. above, this feature is also not taught by Jones.

To set forth a *prima facie* case of obviousness under 35 U.S.C. §103, the applied references must (among other requirements) teach or suggest all of the claim limitations. M.P.E.P., 8th ed., § 2143.03 (rev. May 2004). Because neither Jones nor Sirkar teach or suggest all of the claim limitations, it is respectfully requested that the rejection under 35 U.S.C. §103 be withdrawn.

D. Claims 24 and 60

The Examiner has rejected claims 24 and 60 under 35 U.S.C. 103(a) as being unpatentable over Jones in view of Fung *et al.* (U.S. Patent 6,221,655). Office Action, page 11. The Examiner has set forth this rejection by combining the primary reference with Fung. However, Fung is offered for limited teachings of biological sample filter material, thicknesses, use in a spin filter assembly or with a solid binding matrix. Office Action, page 12, first full paragraph.

Solely to expedite prosecution and not in acquiescence to the rejection, claims 1, 31 and 53 are amended to include the limitation "wherein genomic DNA . . . is sheared by said filter." However, this limitation is not taught or suggested by Fung. As described in Section II. above, this feature is also not taught by Jones.

To set forth a *prima facie* case of obviousness under 35 U.S.C. §103, the applied references must (among other requirements) teach or suggest all of the claim limitations. M.P.E.P., 8th ed., § 2143.03 (rev. May 2004). Because neither Jones nor Fung teach or suggest all of the claim limitations, it is respectfully requested that the rejection under 35 U.S.C. §103 be withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Aaron L. Schwartz, Reg. No. 47,982
FOR Aaron L. Schwartz
Agent for Applicants
Registration No. 48,181

Date: December 27, 2004

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600
347797_1.DOC